

REMARKS

Claims 1-16 are pending in the subject application. In the Office Action of October 25, 2007, claims 1-16 stand rejected. Claims 1-16 have been amended. Support for the amendment to claim 1 can be found at page 3, lines 12-20. Claim 5 has been amended to recite "wherein a portion of the semi-permeable material has the friction enhancing material" for clarity. Claims 1-16 have been amended to correct matters of form. New claims 17-20 have been added and find support throughout the specification, such as at page 3, lines 12-27. Applicants submit that no new matter has been introduced by the amendments to the claims or the addition of the new claims.

A. Rejection of Claim 5 under 35 U.S.C. § 112, second paragraph

Claim 5 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Claim 5 has been amended for clarity to recite "wherein a portion of the semi-permeable material has the friction enhancing material." Accordingly, Applicants request that this rejection be withdrawn.

B. Rejection of Claims 1,2 and 6-9 under 35 U.S.C. § 102(b)

Claims 1, 2 and 6-9 stand rejected under 35 U.S.C. §102(b) as assertedly being anticipated by U.S. Patent No. 5,866,069 to Soto *et al.* (hereinafter "Soto"). Applicants traverse this rejection for the reasons set forth herein.

Claim 1, and claims 2 and 6-9 that depend therefrom, recite a sterilization package for enclosing a device during a sterilization procedure and storing the device in sterile form thereafter. The package comprises a barrier film defining an interior space. The barrier film seals the interior space from contaminating microorganisms. At least a portion of the barrier film is formed of a semi-permeable material which is permeable to sterilizing gases and impermeable to contaminating microorganisms. Furthermore, at least a portion of an outer surface of the package has thereon a friction enhancing material applied in a pattern while not impeding permeation of sterilizing gases.

For a reference to be anticipatory under 35 U.S.C. § 102, it is axiomatic that the reference must teach, either explicitly or inherently, each and every element of the invention as set forth by the claims. Soto does not teach the outer surface of a sterilization package having thereon a friction enhancing material, wherein the friction enhancing material is applied in a pattern while not impeding permeation of sterilizing gases, as recited in amended claim 1. For at least this reason, Soto does not anticipate amended claim 1 or any of the claims dependent therefrom.

Accordingly, Applicants respectfully request withdrawal of the rejection of claims 1, 2 and 6-9 under U.S.C. § 102(b) over Soto.

C. Rejection of Claims 1-9 and 14-16 under 35 U.S.C. § 103(a)

Claims 1-9 and 14-16 stand rejected under 35 U.S.C. §103(a) as assertedly being unpatentable over Soto in view of The Related Prior Art on pages 1-2 of the instant patent application (hereinafter "The Related Prior Art") or U.S. Patent No. 6,986,730 to Hoekstra *et al.* (hereinafter "Hoekstra"). Applicants respectfully traverse the rejection for at least the reasons as set forth herein.

As set forth in MPEP §2142, the key to supporting any rejection under 35 U.S.C. §103(a) is the clear articulation of the reason why the claimed invention would have been obvious. The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, 82 USPQ2d 1385, 1396 (2007) noted that the analysis supporting a rejection under 35 U.S.C. §103(a) should be made explicit. The Federal Circuit has stated that "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."

As further set forth in MPEP §2143, to establish a *prima facie* case of obviousness, the Examiner must articulate a rationale for the rejection. In this matter, it is respectfully submitted that the Examiner has failed to clearly articulate the reasoning in support of the asserted conclusion of obviousness. Based on the Examiner's attempt to arrive at the claimed invention by combining portions of the disclosures in Soto and The Related Prior

Art or Hoekstra, Applicants interpret the Examiner's rationale to be based on an asserted teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to combine these reference teachings to arrive at the claimed invention. See MPEP §2143 (Eighth edition, revision 6, September 2007).

A rejection under §103(a) based on this rationale requires that three basic findings be made:

(1) a finding that there was some teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine the reference teachings in the manner asserted;

(2) a finding that there was reasonable expectation of success; and

(3) whatever additional findings based on the Graham factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness. See MPEP §2143.

In this matter, *i.e.*, where the Examiner contends that the claimed invention is obvious because of a combination of elements gleaned from the reference teachings, the Examiner must explain why it would have been obvious to one of ordinary skill in the art to make the asserted combination. Applicants respectfully submit, however, that there is no reason why one of ordinary skill in the art would make the asserted combination, because there is nothing in the references that would suggest modifying Soto to include the friction enhancing material applied in a pattern while not impeding permeation of sterilizing gases, as recited in amended claim 1, and claims 2-9 and 14-16 that depend therefrom. Moreover, it is submitted that the prior art teaches away from the use of a friction enhancing material applied in a pattern while not impeding permeation into the package.

Soto teaches treating gas-permeable material with a substance including silicon in an amount sufficient to render the material liquid repellent and able to withstand exposure to an oxidizing plasma sterilizing process without losing its repellency (col. 1, lines 66-67 to col. 2, lines 1-3). Notably, Soto discloses at col. 3, lines 57-57 that:

[a]pplication of the silicone can be accomplished by spraying one or both of the opposing sides of a sheet of material utilizing known spraying systems. Silicone can also be applied to the material by exposing the material to an aqueous silicone emulsion comprising silicone or an organic solvent-based system including silicone.

Hence, Soto does not disclose a friction enhancing material applied in a pattern while not impeding permeation of sterilizing gases, but instead teaches coating the entire sheet of material with silicone for liquid repellent purposes.

A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. See MPEP §2141.02(VI). In fact, it has been held that an important indicator of non-obvious is “teaching away” from the claimed invention by the prior art or known by those of ordinary skill. See *U.S. v. Adams*, 383 US 39, 148 USPQ 479 (1966). Indeed, express teaching away from the claimed invention is a *per se* demonstration of lack of *prima facie* obviousness. *In re Dow Chemical Co.*, 837 F.2d 469, 5 USPQ2d 1529 (Fed. Cir. 1988); *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Nielson*, 816 F.2d 1567, 2 USPQ2d 1525 (Fed. Cir. 1987).

Soto, at column 2, lines 10-14, recites “[t]he silicone-containing substance may be applied by spraying, but preferably is applied by subjecting the material to an aqueous emulsion including a silicone. Indeed, one of ordinary skill in the art reading Soto would be led away from using friction enhancing material applied in a pattern while not impeding permeation of sterilizing gases, as recited in amended claim 1 and the claims that depend therefrom.

Furthermore, The Related Prior Art and Hoekstra provide no teaching that, when combined with Soto, would render obvious claims 1-9 and 14-16, as amended. The Related Prior Art teaches a package comprising two film layers with one film formed from TYVEK which is permeable to sterilization gases and impermeable to potentially contaminating microorganisms. Hoekstra teaches a pouch for packaging medical device comprising a first layer formed from a thermoplastic gas impermeable layer and a second layer formed from TYVEK which is a gas permeable microbial barrier defined as permeable to sterilizing gases and impermeable to microbial contaminants.

The Related Prior Art and Hoekstra fail to teach or suggest a sterilization package comprising a friction enhancing material placed in a pattern over a sterilization package while not impeding permeation of sterilizing gases, as recited in claim 1.

Thus, a *prima facie* case of obviousness for claims 1-9 and 14-16, as amended, in view of the combination of teachings of Soto in view of The Related Prior Art or Hoekstra has not been established. Accordingly, Applicants respectfully request the withdrawal of the rejection of claims 1-9 and 14-16 under 35 U.S.C. §103(a) in view of Soto in view of The Related Prior Art or Hoekstra.

D. Rejection of Claims 1-16 under 35 U.S.C. § 103(a)

Claims 1-16 stand rejected under 35 U.S.C. §103(a) as assertedly being unpatentable over The Related Prior Art or Hoekstra in view of the European Publication No. 0304255 to Katila (hereinafter "Katila"). In view of the amendment to claim 1, as discussed herein, Applicants assert that the Examiners rejections are rendered moot, and respectfully traverse the rejection for at least the reasons as set forth herein.

The Related Prior Art and Hoekstra are clearly distinguishable from the recited claims for at least the reasons set forth herein. Furthermore, nothing in Katila when combined with these refererenes would render obvious claims 1-16.

As stated in the MPEP §2143.02, "a reasonable expectation of success is required to support a *prima facie* case of obviousness." *In re Clinton*, 527 F.2d 1226, 1228, 188 USPQ 365, 367 (CCPA 1976). Applicants content that one of ordinary skill in the art would not have a reasonable expectation of success of arriving at the claimed invention by combining conventional sterilization packaging, as taught by The Related Prior Art and Hoekstra, with conventional foil sheets, as taught by Katila. One of ordinary skill in the art reading Katila would not be motivated to use the conventional foil sheets of Katila to wrap the sterilization packages of The Related Prior Art or Hoekstra to promote a frictional surface because the conventional foil sheets would impede permeation of sterilizing gases through the semi-permeable material of the sterilization packaging. The conventional foil sheets of Katila are said to wrap packages of perishable products, such as food, fertilizer,

and timber (col. 1, lines 47-56). It is respectfully submitted that one of ordinary skill in the art reading Katila would not combine its teachings with that of The Related Prior Art or Hoekstra to provide a sterilization packaging comprising friction enhancing material that is applied in a pattern to enhance friction without impeding the permeation of sterilizing gases, as recited in claims 1-16. Indeed, Katila can be said to lead one of ordinary skill in the art away from the invention recited in claims 1-16 because such a modification would result in the destruction of the intended function of the sterilization package; namely to be permeable to sterilizing gases. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed.Cir. 1984).

Thus, a *prima facie* case of obviousness for claims 1-16 in view of the combination of teachings of The Related Prior Art or Hoekstra further in view of Katila has not been established. Accordingly, Applicants respectfully request the withdrawal of the rejection of claims 1-16 under 35 U.S.C. §103(a) in view of The Related Prior Art or Hoekstra further in view of Katila.

E. Rejection of Claims 1-16 under 35 U.S.C. § 103(a)

Claims 1-16 stand rejected under 35 U.S.C. §103(a) as assertedly being unpatentable over The Related Prior Art or Hoekstra in view of the European Publication No. 0863087 to Hoeft (hereinafter "Hoeft"). Applicants respectfully traverse the rejection for at least the reasons as set forth herein.

Applicants respectfully submit that the combined teachings of The Related Prior Art or Hoekstra in view of Hoeft does not form the basis for an obviousness rejection because one of ordinary skill reading the references would not recognize that the claimed combination of elements would lead to the claimed results. The Related Prior Art and Hoekstra do not teach the use of friction enhancing material and are clearly distinguishable from claims 1-16 for the reasons set forth in *Section C*.

The Examiner states that Hoeft teaches "a package comprising an outer surface and an anti-slip layer formed from a silicone based material disposed on the outer surface of the package to prevent the package slipping when the package is stacked with other

packages (Office Action, page 4, paragraph 3). However, Hoeft, at pages 4, lines 16-19, teaches:

[i]t has been further found that the silicone based material according to the present invention is also water repellent. Consequently, a package treated with the silicone based material is more resistant to outside influences, like water and moisture.

Therefore, one of ordinary skill in the art reading Hoeft would understand that a package treated with the silicon based material of Hoeft would also be resistant to outside influences such as sterilizing gases, thus, impeding permeation of sterilizing gases through the semi-permeable material of the sterilization packaging. Thus, one of ordinary skill in the art would not combine the teachings of Hoeft with the teachings of The Related Prior Art or Hoekstra, because such a modification would result in the destruction of the intended function of the sterilization package; namely to be permeable to sterilizing gases. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed.Cir. 1984). At the very least, one of ordinary skill in the art would be lead to believe that applying the packaging of Hoeft would impede the permeation of the sterilization gases of sterilization package of the The Related Prior Art or Hoekstra.

Thus, a *prima facie* case of obviousness for claims 1-16 in view of the combination of teachings of The Related Prior Art or Hoekstra further in view of Hoeft has not been established. Accordingly, Applicants respectfully request the withdrawal of the rejection of claims 1-16 under 35 U.S.C. §103(a) in view of The Related Prior Art or Hoekstra further in view of Hoeft.

F. Rejection of Claims 1-16 under 35 U.S.C. § 103(a)

Claims 1-16 stand rejected under 35 U.S.C. §103(a) as assertedly being unpatentable over The Related Prior Art or Hoekstra in view of the German Patent No. 1,779,373 to Vollmer (hereinafter "Vollmer"). Applicants respectfully traverse the rejection for at least the reasons as set forth herein. A full translation of Vollmer is enclosed herein.

The Examiner contends that the claimed invention is obvious because of a combination of elements gleaned from the reference teachings. Applicants respectfully

submit, however, that there is no reason why one of ordinary skill in the art would make the asserted combination, because there is nothing in any of the references that would suggest modifying The Related Prior Art or Hoekstra to include the friction enhancing material applied in a pattern on sterilization packaging while not impeding permeation of sterilizing gases. Claim 1 and The Related Prior Art or Hoekstra are clearly distinguished for the reasons set forth herein. Vollmer provides no teaching of semi-permeable sterilization packaging and provides no teaching how the anti-skid coating can be applied to a "sack or bag made of thermoplastic material" in order to arrive at the invention recited in claims 1-16. In particular, claims 1-16 recite a sterilization packaging comprising a friction enhancing material that is applied in a pattern to enhance friction without impeding the permeation of sterilizing gases. The Subject Application is directed to a semi-permeable packaging and the application of friction enhancing material to the packaging such that permeation of sterilizing gases is not impeded. Vollmer does not recognize this problem, and provides no solution to address permeability and friction enhancement. Accordingly, one of skill in the art would not be taught to apply Vollmer's teaching to arrive at claims 1-16 of the Subject Application.

A prior art reference must be considered in its entirety. See MPEP §2141.02(VI). The Related Prior Art, Hoekstra, and Vollmer provide no discussion of providing a sterilization package that can exhibit friction enhancement while not impeding permeation of sterilizing gases. Any assertion to the contrary is improper hindsight reconstruction, using only the teaching of the Subject Application.

Thus, a *prima facie* case of obviousness for claims 1-16 in view of the combination of teachings of The Related Prior Art or Hoekstra further in view of Vollmer has not been established. Accordingly, Applicants respectfully request the withdrawal of the rejection of claims 1-16 under 35 U.S.C. §103(a) in view of The Related Prior Art or Hoekstra further in view of Vollmer.

G. New Claims 17-20

For at least the reasons set forth above, new claims 17-20 are believed to be patentable in view of the cited references. None of the references discloses either explicitly or inherently claims 17-20.

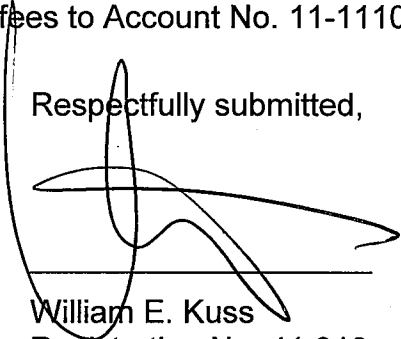
CONCLUSION

For at least the reasons discussed above, Applicants respectfully request reconsideration of the rejections of claims 1-16 and allowance of all claims 1-20. Applicants respectfully submit that the present claims are clearly distinguished over the prior art of record and are in proper form for allowance.

If the undersigned can be of assistance to the Examiner regarding any of the above, please contact the undersigned at the number set forth below. Applicants submit that if any additional fee is necessary for consideration of this Response, the Commissioner is hereby authorized to charge the additional required fees to Account No. 11-1110.

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Date

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